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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP			MUTSCHLER, BRIAN L	
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WASHINGTON, DC 20037-1526			PAPER NUMBER	
			1753	

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,329

Applicant(s)

INABA ET AL.

Examiner

Brian L. Mutschler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Comments

1. It is noted that the claims, other than claim 1, do not positively cite a source for producing a laser beam. As apparatus claims, process limitations define the structure only insofar as the apparatus is capable of performing the recited process.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "**100**" has been used to designate both the center of transmitted light (see page 26 at line 13) and light spots (see page 26 at line 27).

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: **52** (Figure 1); **7** and **8** (Figure 2); **104** and **105** (Figures 7C and 9B); **140**, **142**, and **145** (Figure 12A); and **142** and **145** (Figure 12B).

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: **172** and **173** (see page 36, at line 23).

5. The drawings are objected to because in Figure 13A, the reference sign **131** should be changed to **161**.

6. The drawings are objected to because Figure 18 is not shown (see page 16, line 26 and page 17, line 1).

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7. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

8. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested:

CAPILLARY ARRAY ELECTROPHORESIS APPARATUS.

9. The specification contains many grammatically awkward and incorrect phrases. Applicant's assistance in correcting the specification is kindly requested.

Claim Objections

10. Claims 1-15 are objected to because of the following informalities:

- a. In claim 1 at lines 1-2, the phrase "in which laser beam is irradiated" is grammatically incorrect. The phrase also appears in claims 2 and 3.
- b. In claim 1 at line 4, the phrase "characterized, in that" should be changed to --characterized in that--. The same phrase also occurs in claims 2-15.
- c. In claim 2 at line 8, please change "is arranged not in parallel" to --is not arranged in parallel--.

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- d. In claim 4 at lines 3-4, the phrase "overlap near the center of the capillary array each other" is grammatically unclear.
- e. In claim 5 at line 6, the word "spectrumed" is not a defined term in the art.
- f. In claim 10 at lines 2-3, it is suggested that the phrase "includes a CCD (Charge Coupled Device) camera and pixel grid of the CCD camera is substantially parallel" be modified to clarify the wording of the limitation.

The following phrases are suggested: --includes a CCD (Charge Coupled Device) camera having a pixel grid, wherein the pixel grid of the CCD camera is substantially parallel-- or --includes a CCD (Charge Coupled Device) camera, and the CCD camera has a pixel grid substantially parallel--. The same phrase also occurs in claim 14.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 12. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "in which laser beam is irradiated to either one or both end capillaries at both sides of a capillary array" in lines 1-2. This limitation is indefinite for several reasons. First, the limitation is a process limitation that does not

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structurally identify the apparatus. Second, the limitation is indefinite because it is not clear where the laser beam is irradiated. What does “both end capillaries at both sides of a capillary array” mean? Does the term “ends” refer to the ends of a capillary or the outermost capillary located on the periphery of a planar capillary array? Third, how is a single “laser beam” irradiated at both sides of a capillary array? Due to the lack of clarity in the claim, the claim was interpreted in light of the specification to have at least one laser beam for irradiating either one or both of the outermost capillaries in a planar array, i.e., the laser is positioned such that the beam propagates successively through adjacent capillaries. Similar limitations also appear in claims 2 and 3, which are also indefinite for the reasons given above. The same applies to dependent claims 4-15.

Claim 1 recites the limitation “the adjacent capillary” in line 4. There is insufficient antecedent basis for this limitation in the claim. The same applies to dependent claims 12-15.

Claim 2 recites the limitations “the two laser beams” and “the adjacent capillaries” in lines 4-6. The claim also recites the limitation “at least one of the irradiated laser beams” in lines 7-8. There is insufficient antecedent basis for these limitations in the claims. Additionally, what is the relationship between the laser beam recited in line 2 and the two laser beams recited in line 5?

Claim 3 recites the limitations “the two laser beams” and “the adjacent capillaries” in lines 4-6. The claim also recites “the orthogonal projections” and “the two incident laser beams” in lines 7-8. There is insufficient antecedent basis for these limitations in the claim. The same applies to dependent claims 4-11.

Claim 4 recites the limitations "the centers" in lines 2-3 and "the two opposing laser beams" in line 3. There is insufficient antecedent basis for these limitations in the claim. Additionally, does the term "centers" refer to the center of the cross-section of the beam, or the center of the longitudinal length of the beam? The same applies to dependent claims 5-11.

Claim 5 recites the limitation "the respective opposing two laser beams" in lines 5-6. There is insufficient antecedent basis for this limitation in the claim. Claim 5 also recites the phrase "an excitation light source is spectrumed" in line 6. What does the term "spectrumed" mean? It appears that the term "diffracted" would be more appropriate. The same applies to dependent claims 6-11.

Claim 6 recites a process limitation involving two condenser lenses (see line 3). What is the relationship between the condenser lenses and the capillary array apparatus? Claim 6 also recites the limitations "the opposing two incident laser beams" and "the opposing two laser beams" in lines 3-5. There is insufficient antecedent basis for these limitations in the claim. The same applies to dependent claims 7 and 8.

Claim 6 is indefinite because it appears to contradict the limitations recited in claim 3. In claim 3, orthogonal projections of the two incident laser beams are not in parallel, which means the two beams themselves are not parallel. However, claim 6 recites, "the two beams are substantially in parallel" (see lines 5-6). How can the two beams be parallel and not parallel in the same apparatus? The same applies to dependent claims 7 and 8.

Claim 7 recites the limitation "the laser beam condenser lenses" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 8 recites "a laser beam optical axis adjusting jig which is constituted by a set of two plates in each of which two holes ... are formed" in lines 2-4 and "the two parallel laser beams" in line 5. What is the structure of the capillary array apparatus in relation to the adjusting jig? Claim 3 recites a limitation that the orthogonal projections of the laser beams are not parallel, which appears to correspond to Figure 13C. How do the two parallel beams of claim 8 relate to the non-parallel beams of claim 3? Additionally, as shown in Figure 13A, each of the two plates has *four* holes due to the asymmetry of the beams. How does the adjusting jig function to adjust the optical axis of the laser beam when two non-parallel laser beams are formed? It is noted that Figures 6A-6C demonstrate the use of two-holed plates for a parallel beam apparatus.

Claim 8 recites the limitation "the two parallel laser beams" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Regarding claims 9 and 13, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 10 recites the limitation "pixel grid of the CCD camera is substantially parallel to the laser beam optical axis" in lines 3-4. There is insufficient antecedent basis for "the laser beam optical axis" in the claim. The claim is also indefinite because claim 3 recites the limitation that the orthogonal projections of the two laser beams are not parallel. Which laser beam optical axis does the pixel grid parallel?

Claim 12 is indefinite because it recites a process involving the removal of two condenser lenses, which are not identified in the claim from which claim 12 depends. What is the relationship between the capillary array apparatus of claim 1 and the condenser lenses of claim 12?

Claim 12 recites the limitations "the opposing two incident laser beams" in lines 2-3 and "the opposing two laser beams" in line 3. There is insufficient antecedent basis for these limitations in the claim. Claim 1 does not recite two laser beams.

Claim 13 recites the limitation "the fluorescent detection means" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite a detection means.

Claim 14 recites the limitation "the fluorescent detection means" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-4 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Anazawa et al. (U.S. Pat. No. 5,938,908).

Regarding claims 1-3, Anazawa et al. disclose a capillary array electrophoresis system comprising a plurality of parallel capillaries 1 arranged in a planar array (fig. 4).

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A laser beam **2**, which is capable of being split into two beams, passes sequentially through and irradiates all of the capillaries **1** (figs. 10A and 10B). The apparatus is capable of substantially preventing reflections by the half-mirror **29** and by placing the array in water (col. 3, lines 22-31). As shown in Figures 2 and 3, the laser beams do not propagate through the array linearly due to refraction within the capillaries. Lenses **4**, including spherical lenses, are used to transmit the beams through the entire array (figs. 3 and 4; col. 4, line 58 to col. 5, line 12).

Regarding claim 4, when two incident laser beams are used, the beams substantially overlap near the center of the array (fig. 10B).

Regarding claim 12, the two laser beams **2**, **2'** are substantially parallel to one another and perpendicular to the axes of the capillaries (figs. 4 and 10B).

Regarding claims 13 and 14, the device comprises a fluorescent detection means having a wavelength dispersion means (prism or filter **7**) set perpendicular to the laser beam optical axis and a CCD camera **9**, having a 1D or 2D array, parallel to the optical beam (fig. 4).

Since Anazawa et al. teach all of the structural limitations recited in the instant claims, the reference is deemed to be anticipatory.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 5-7, 9, and 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Anazawa et al. (U.S. Pat. No. 5,938,908) in view of Dovichi et al. (U.S. Pat. No. 5,567,294).

Anazawa et al. disclose an apparatus having the limitations recited in claims 1-4 and 12-14 of the instant invention, as explained above in section 14.

Regarding claims 5, 9, and 10, the device comprises a fluorescent detection means having a wavelength dispersion means (prism or filter **7**) set perpendicular to the laser beam optical axis and a CCD camera **9**, having a 1D or 2D array, parallel to the optical beam (fig. 4).

Regarding claim 6, the two laser beams **2**, **2'** are substantially parallel to one another and perpendicular to the axes of the capillaries (figs. 4 and 10B).

The apparatus of Anazawa et al. differs from the instant invention because Anazawa et al. do not disclose the following:

- a. The detection means uses a grating, as recited in claim 5.
- b. The apparatus comprises a position adjusting mechanism of the laser beam condenser lenses, as recited in claim 7.

Regarding claim 5, Dovichi et al. disclose a multiple capillary apparatus comprising a CCD fluorescence detector (fig. 2). The detector uses a filter **139**, which can be a filter, grating, or prism (col. 5, lines 29-55).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the prism or filter of Anazawa et al. to use a

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grating as taught by Dovichi et al. because Dovichi et al. teach that filters, gratings, and prisms can be used equivalently to filter the fluorescence from specific dyes.

Regarding claim 7, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the lenses in the apparatus of Anazawa et al. to be adjustable because making an object adjustable is a non-obvious modification. See *In re Stevens*, 212 F.2d 197, 101 USPQ 284 (CCPA 1954).

Adjustable lenses would be a desirable modification to one skilled in the art because adjustable lenses allow lasers to be properly aligned.

17. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anazawa et al. (U.S. Pat. No. 5,938,908) in view of Dovichi et al. (U.S. Pat. No. 5,567,294), as applied above to claims 5-7, 9 and 10, and further in view of Staver et al. (U.S. Pat. No. 5,621,831).

Anazawa et al. and Dovichi et al. describe an apparatus having the limitations recited in claims 5-7, 9, and 10 of the instant invention, as explained above in section 16.

The apparatus described by Anazawa et al. and Dovichi et al. differs from the instant invention because they do not disclose the use of a laser beam optical axis adjusting jig, as recited in claim 8.

The use of an adjusting plate with holes is a known means for aligning lasers. For example, Staver et al. disclose the use of a plate **20** having either a hole or a mark **30** to align the laser (fig. 2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the apparatus described by Anazawa et al. and Dovichi et al. to use a adjusting jig comprised of plates with holes as taught by Staver et al. because an adjusting jig allows the accurate alignment of a laser.

18. Claims 11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anazawa et al. (U.S. Pat. No. 5,938,908) and Dovichi et al. (U.S. Pat. No. 5,567,294), and further in view of FR 2,774,472, herein referred to as FR '472.

Anazawa et al. and Dovichi et al. describe an apparatus having the limitations recited in claims 1-7, 9, 10, and 12-14, as explained above in sections 14 and 16.

The apparatus described by Anazawa et al. and Dovichi et al. differs from the instant invention because they do not disclose the use of a light interrupting plate disposed to interrupt either transmitted or reflected light, as recited in claims 11 and 15.

FR '472 discloses a detector for a capillary array electrophoresis apparatus comprises a laser **F**, a plurality of capillaries **C**, and a detector **6** (fig. 2). FR '472 also discloses a mask to minimize the background noise coming from the scattering of the laser beam **F** or the fluorescence of the walls of the capillaries **C** or the surrounding medium (page 6, lines 15-18). U.S. Pat. No. 6,613,212 B1 is an English language version of FR '472.

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the apparatus described by Anazawa et al. and Dovichi et al. to use a mask as taught by FR '472 because the mask minimizes background noise coming from the scattering of the laser beam.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 1 and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/098,330 in view of Foley et al. (U.S. Pat. No. 6,592,733).

The copending application recites a capillary array irradiated by a laser beam at one capillary at the end of the array or both capillaries at either end of the array, and further comprising scattered light shielding means (claim 3).

The claims of the copending application differ from the instant invention because the copending application does not disclose the following:

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- a. Laser beam condensing means, as recited in claim 1.
- b. Fluorescent detection means having a wave length dispersion means, as recited in claim 13.
- c. Fluorescent detection means having a CCD camera and pixel grid set parallel to the laser beam optical axis, as recite in claim 14.

Foley et al. disclose a capillary array apparatus comprising a laser beam irradiating capillary array comprising a laser beam and a condensing lens **122** to focus the laser beam on the capillary array (fig. 2). The apparatus further comprises a fluorescent detection means having a filter and a CCD camera arranged parallel to the optical beam axis of the laser (fig. 2; col. 5, lines 29-59).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the apparatus claimed in the copending application to use a condensing means as taught by Foley et al. because the condensing means allows the excitation source to be focused on the capillary array.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the apparatus of the copending application to use a fluorescent detection means as taught by Foley et al. because the fluorescent detection means allows the sample separated in the capillaries to be detected and measured.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references disclose related systems.

U.S. Pat. No. 5,366,603 Middendorf et al.

U.S. Pat. No. 5,600,444 Tong

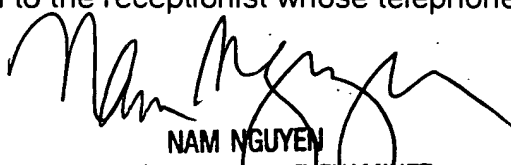
U.S. Pat. No. 5,790,727 Dhadwal et al.

Ueno et al. "Simultaneous Monitoring of DNA Fragments Separated by Electrophoresis in a Multiplexed Array of 100 Capillaries," *Anal. Chem.* 1994, 66, 1424-1431.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian L. Mutschler whose telephone number is (703) 305-0180. The examiner can normally be reached on Monday-Friday from 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

blm
December 2, 2003